REMARKS

Claims 2 to 31 continue to be under consideration.

Claims 1 and 32 are being cancelled.

Claims 2 to 17, 22, and 27 are amended.

Claims 33 and 34 are newly introduced.

Claim 33 is based on claim 18, the specification and the drawings, in particular Figs. 1 and 4 and Figs. 2 and 3.

Claim 34 is based on claim 18, the specification and the drawings.

The Office Action refers to the Information Disclosure Statement

The *information disclosure statement* (IDS) that was submitted on 10/05/2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

Applicants appreciate the consideration which has been given to the Information given to the Information Disclosure Statement.

The Office Action refers to the Specification

The *title of the invention* is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The present amendment introduces a new title of the application as follows: Ultrasonic Wound Treatment Apparatus.

The *disclosure stands objected to* because of the following informalities: The specification does not disclose a description of the new Figure 2a, and does not contain any reference to the new reference numeral "30".

Appropriate correction is required.

The description has been amended to incorporate a description of Fig. 2a. The reference numeral "30" has been removed from the application.

The Office Action refers to Drawings.

The drawings (Figure 2a) are objected to because it constitutes new matter. Applicant has entered a new drawing to add the sonotrode channel element, the only disclosure present was in originally filed claim 18 and the specification page 6, paragraph 3, in which the channel is disclosed to be within the sonotrode and connected to the flushing line. The new drawing shows a specific spatial, length, connection element of the sonotrode channel to the flushing line which have no basis in the originally filed disclosure and thus are new matter.

The present amendment submits a revised Fig. 2a, where the reference numeral 30 has been eliminated and wherein the channel is only indicated schematically with dashed lines.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application.

Applicants are submitting with this amendment a corrected Fig. 2a on a Replacement Sheet.

Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency.

The present amendment introduces descriptive language relating to Fig. 2a into the brief description of the drawing.

Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: reference numeral "30". Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of

the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Applicants are submitting together with the present amendment a replacement sheet for Fig. 2a, which shows the channel only schematically.

The Office Action refers to Claim Rejections - 35 USC § 102.

Claims 1,4, 6,10, and 32 stand rejected under 35 U.S.C. 102(b) as being anticipated by Dieras et al. (USPN4,804,364). Dieras et al. discloses an apparatus for the curettage or exeresis of biological tissue by means of ultrasonic vibration.

The present amendment cancels claims 1 and 32 and changes the dependency of claims 4, 6, and 10.

Regarding claims 1, 4, 6,10, and 32, Dieras et al. discloses a medical treatment apparatus (Figure 1) capable of being used for wound treatment with a hand piece (18) equipped with an ultrasound vibration generator (6) with electric connection means (11) and **a** sonotrode (14) attached to the hand piece (18), characterized in that wherein **a** channel (lumen of 14) is disposed within the

sonotrode for feeding a medical flushing liquid to a tip of the sonotrode (near 2) via a flushing line (4) connector; wherein an adaptation sleeve (7) can be slid over the sonotrode (14) of the medical treatment apparatus and wherein the adaptation sleeve (7) can be attached at the hand piece (near 19), wherein the adaptation sleeve (7) is equipped with a connector (lumen near 15) for receiving a suction hose (Figures 1-7, cols 1-2).

The reference Dieras et al. may very well describe a medical apparatus where a sleeve is slid over a sonotrode and which shows connections for a flushing line and for a suction line. The reference Dieras et al does not present any suggestion that during treatment smoke and fumes are suctioned off from the treatment zone by the apparatus of the reference Dieras et al. If no flushing liquid is fed in, the reference Dieras does not say what happens.

The Office Action refers to Claim** Rejections - 35 **USC** § **103.

Claims 5, 7,11,13,18-24, 26, and 30 are rejected under 35 U.S.C 103(a) as being unpatentable over Dieras et al. (USPN4.804.364) in view of Christ et al. (USPN5,984,889). Dieras et al. meets the claim limitations as described above except for a valve within the flushing line, operating at a specific frequency range, and a screw type sleeve connection.

However, Christ et al. teaches an apparatus and method for ultrasonic tissue intervention.

Applicants respectfully traverse. The present invention is directed to an ultrasonic wound treatment apparatus. The reference Dieras et al. (column 1, lines 8

to 11) is directed to an instrument vibrating at ultrasound frequencies, associated with one or more irrigating fluids placed in cavitation and absorbed by a coaxial suction system. The reference Christ et al. (column 1, lines 8 and 9) is directed to a handpiece for ophthalmic surgical procedures. The references Dieras et al. and Christ et al. Are not directed to the treatment of wounds as is the present application and therefore there is no basis to combine the references Dieras et al. and Christ et al to obtain a wound treatment apparatus.

In addition, bad smelling and damaging fume gases can be generated in connection with the use of such wound treatment apparatus This specification, page 2, second paragraph), which fume gases can interfere with the sight of the operator and can lead to an endangerment of the health by the release of damaging aerosols, toxic gases and human viruses. Consideration to the removal of fume gases is given in the present application by having a suction tube (11), an adapter sleeve (10), a receiver part (12) independent from the hand piece (1), a hose connection (13) and a suction hose (14). Beginning with the receiver part (12) a relatively wide tube is available according to the present invention for simultaneous removal of fume gases together with waste medical flushing liquid. In clear contrast the Dieras et al. reference teaches to have a ring-shaped cross section (fig. 1) or a very small cross-section of conduit 25 in comparison with the irrigation conduit 24.

The reference Christ et al. teaches in column 5, lines 22 to 27 : "More particularly, the needle 14 and horn 24 may include a bore 90 therethrough, said bore being connected to an aspiration tube 94 to which a vacuum is applied in a conventional manner by the phacoemulsification machine, again being of any suitable design and not part of the present invention.". Therefore the references Dieras et al. and Christ et al. agree to guide the discharge liquid through a centered conduit in the respective hand piece, whereas the claims of the present

application require that there is a receiver part 12 branching off from the adaptation sleeve 10.

Regarding claims 5, 7,11,13,18-24, 26, and 30, Christ et al. teaches a medical treatment apparatus (Figure 2) capable of being used for wound treatment with a hand piece (28) equipped with an ultrasound vibration generator (32) operating at 20-100kHz (col 4, In 25-40) and a sonotrode (20) attached to the hand piece (28), characterized in that wherein a channel (lumen of 20) is disposed within the sonotrode for feeding a medical flushing liquid to a tip of the sonotrode (near 20) via a flushing line (near 126) connector with a valve interface; wherein an adaptation sleeve (7) can be slid over the sonotrode (14) of the medical treatment apparatus and wherein the adaptation sleeve (12) can be attached at the hand piece (near 28) via a threaded connection (Figures 1-4).

Applicants respectfully disagree.

The reference Christ et al. does not teach a medical treatment apparatus, but teaches a phacoemulsification handpiece.

There is no channel (lumen of 20) disposed within the sonotrode for feeding a medical flushing liquid to a tip of the sonotrode (near 20). In contrast, according to the reference Christ et al. and as recited above, the bore 90 is connected to an aspiration tube 94 and no medical flushing liquid is fed through the bore 90 to the tip of a sonotrode. The flushing line (near 126) is connected to the outlets 64 and not to the inside of the sonotrode and its tip 44.

The element 12 of the reference Christ et al is no adaptation sleeve with receiver part in the sense of the present application but instead is a tip portion 12 of the handpiece. The receiver part 12 of the adaptation sleeve 10 according to the present invention is not present in the reference Christ et al.

Contrary to the allegation in the Office Action, no adaptation sleeve 7 is seen in the reference Christ et al.

At the time of the invention, it would have been obvious to add the fluid control valve and the threaded sleeve connection in order to add fluid control and easy cleaning and disassembly of the unit.

Applicants respectfully disagree. There is no motivation to apply any devices from a phacoemulsification handpiece of the reference Christ et al. to the ultrasound apparatus of the reference Dieras et al. It is not recognized what a fluid control valve has to do with easy cleaning and/or disassembly of the unit.

The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Christ et al. (cols 1-2).

The anology the references Dieras et al. and Christ et al. have with the present application is that they involve ultrasound and sonotrodes. However while the present application is directed to a wound treatment apparatus, the reference Dieras et al. is directed to suctioning of disaggregated tisses and the reference Christ et al. is directed to a phacoemulsification handpiece. The apparatuses of the

reference Dieras et al. and Christ et al. are not suitable to replace the wound treating apparatus of the present invention.

The Office Action refers to Claim Rejections - 35 USC § 103.

Claims 2, 8, and 27-29 are rejected under 35 U.S.C 103(a) as being unpatentable over Dieras et al. (USPN4.804.364) in view of Christ et al. (USPN5.984.889) or (Dieras et al. (USPN4.804.364)).

Applicants respectfully traverse.

Dieras et al. or the modified Dieras et al. meets the claim limitations as described above except for the HEPA filter separator trap system.

However, Mallet et al. teaches a microderm suction apparatus.

Applicants respectfully disagree

Regarding claims 2, 8, and 27-29, Mallet et al. teaches a suction (10) (Figure 1) filter system (32) containing a HEPA filter (203) trap (Figure 9).

Applicants respectfully disagree. The element 32 of the Mallett et al. references a crystal supply station (reference Mallett et al., column 3, line 55) and not a filter system as alleged in the Office Action. The element 203 of the Mallett et al. reference is designated as a filter 203 (column 7, line 33) or as an exit filter 203 (column 7, line 37), and not as a HEPA filter as alleged in the Office Action.

As far as a HEPAfilter is concerned, the reference Mallett et al. states in column 4, lines 33 to 35: "Of particular interest in the crystal supply station 32 is a bypass valve 68 which extends between the HEPA filter 58 and the supply lumen 67 of the handpiece 16.". The element 58 in Fig. 2 of the Mallett et al. reference is drawn completely different from the element 203 in Fig. 9 of the Mallett et al. reference. While element 58 is indicated to be a HEPA-filter, the different drawing of element 203 can be taken as an indication that the filter 203 is not a HEPA filter.

Furthermore, the reference Mallett et al. is directed to an apparatus for microdermabrasion and for endermologie massage. According to the Mallett et al. reference, column2, lines 33 to 37: "The first air stream is directed through a source of crystals which are introduced into the first air stream to provide a flow of crystals which is sent to the microdermabrasion handpiece." This teaching of the Mallett et al. reference clearly directs away from the present invention, which employs a medical flushing liquid and not a first air stream with crystals.

At the time of the invention, it would have been obvious to add the filter trap system of Mallet et al. to the system of Dieras et al. or the modified Dieras et al. in order to contain potentially harmful body fluids from the body.

Applicants respectfully disagree.

According to the reference Mallett, column 7, lines 34 to 38: "Since this exit air forms the first air stream which in turn must pass through the 3-way mode selector valve 29 and the vacuum pump 21, it is important that the crystals 63, and any fragments thereof, be removed by this exit filter 203.".

It appears that the first air stream with crystals is a precondition for the use of exit filter 203. Since the present invention does not employ a first air stream with crystals but a medical flushing liquid, a filter for separating crystals from a first air stream is not sensible in the context of the present invention.

The references are analogous in the art and with the instant invention; therefore, a combination is proper.

Applicants respectfully disagree. While the present invention is directed to an ultrasonic wound treatment apparatus, there is no ultrasonic apparatus taught in the Mallett et al. reference. Applicants urge that skin abrasion and suction massage are not analogous to ultrasonic wound treatment.

Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Mallet et al. (cols 1-2).

Applicants urge that a person of ordinary skill in the art would not have combined the teachings of the reference Mallett et al. requiring a source of crystals, a microdermabrasion handpiece, a suction massage handpiece, a valve for alternatively directing the stream of air, and introduction of the crystals into the first air stream with any other reference for obtaining the present invention.

*The Office Action refers to Claim Rejections - 35 **USC** § **103**.*

Claims 3, 9,12,14-17, 25 and 31 are rejected under 35 U.S.C 103(a) as being unpatentable over Dieras et al. (USPN4,804,364) in view of Christ et al. (USPN5.984.889) or (Dieras et al. (USPN4.804.364)). Dieras et al. or the modified Dieras et al. meets the claim limitations as described above except for the opacity of the fluid lines and ultrasound drive materials.

Regarding claims 3, 9, 12,14-17, 25 and 31, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the fluid tubes of an opaque or non-opaque substance in order to see the contents or get optimal pressure resistance depending on the material selected and it would have been obvious to substitute the piezoelectric drive with a magneto drive since both are well known ultrasound generation means, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

As the intended use is not to look through a transparent adaptation sleeve (10) but ultrasonic wound treatment, a person of ordinary skill in the art would not employ a non-opaque material when there are advantageous other materials are available like stainless steel. Thus the employment of non-opaque materials for the adaptation sleeve (10) is certainly non-obvious.

With respect to piezoelectric and magneto drive, the applicants' specification on page 2, lines 4 to 7 states: 'Here preferably the piezoceramic

principle is employed since the piezoceramic princiole generates much less heat as compared with the magnetostrictive principle.'.

Reconsideration of all outstanding rejections is respectfully requested.

All claims presently submitted are deemed to be in allowable form and a Notice of Allowance is earnestly solicited.

Respectfully submitted,
Holger Söring et al.

By: Horst M Kasper

Horst M. Kasper, their attorney
13 Forest Drive, Warren, N.J. 07059
Tel.(908)757-2839 Fax: (908)668-5262
Reg.No. 28559; Docket No.: SOR205

/rep/am